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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/666,144	09/20/2000	Vaijayanti A. Kumar	273944	5793

26694 7590 07/21/2006

VENABLE LLP  
P.O. BOX 34385  
WASHINGTON, DC 20045-9998

EXAMINER

ANGELL, JON E

ART UNIT PAPER NUMBER

1635

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/666,144

Applicant(s)

KUMAR ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-20 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-20 and 24-26 is/are allowed.
- 6) ☒ Claim(s) 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The amendment filed 4/27/2006 is acknowledged and has been entered. Claims 14-20, 22-26 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

#### ***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 23 have been amended according to the 4/27/2006 communication such that claims 22 and 23 now encompass a compound according to claim 14 or 15, respectively, wherein said compound is "a single or double stranded polynucleotide DNA or RNA". This new recitation renders the claims indefinite because claims 14 and 15 are drawn to peptide nucleic acid (PNA) compounds, not polynucleotide DNA or RNA compounds. PNA compounds are structurally distinct from DNA and RNA polynucleotide compounds because PNA compounds comprise a modified backbone aminoethylglycine units while DNA and RNA molecules comprise a sugar-phosphate backbone. For instance, the specification on page 2 specifically

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states, "In these compounds, a linear amide chain composed of repeating aminoethylglycine units to which nucleobase ligands are attached replaces the cyclic sugar-phosphate backbone of DNA and are amenable for easy preparation by solid phase peptide synthesis." Therefore, neither claims 14 or 15 encompass polynucleotide DNA or RNA molecules; rather, claims 14 and 15 encompass PNA molecules which are structurally and functionally distinct from polynucleotide DNA/RNA molecules. Since claims 14 and 15 do not encompass polynucleotide DNA or RNA molecules, and considering that claims 22 and 23 are drawn to the compound of claims 14 or 15 which are polynucleotide RNA or DNA molecules, claims 22 and 23 are indefinite.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

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MPEP §2163.06 notes:

*If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).*

MPEP §2163.02 teaches that:

*Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.*

MPEP §2163.06 further notes:

*When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

In the instant case claims 22 and 23 were added as new claims in the amendment filed 4/11/2005. In the 4/11/2005 amendment, claims 22 and 23 were drawn to a process for sequence specific recognition of a single or double stranded polynucleotide DNA or RNA by oligomers as in claim 14 or claim 15, respectively, using compounds of formulae 4a and 6a. Claims 22 and 23 were then amended by the amendment filed 9/29/2005 to a process for sequence specific recognition of a single or double stranded polynucleotide DNA or RNA compound according to claim 14 or claim 15, respectively, using compounds of formulae 4a and 6a. Therefore, the claims were amended from a process of sequence specific recognition of a polynucleotide using the oligomers of claims 14 or 15 to a process of sequence specific recognition of the compounds of claims 14 or 15 using the monomers of formula 4a or 6a. Looking to the specification for

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support for processes for using the compounds of formula 4a and 6a, it is clear that the specification contemplates using the compounds of 4a and 6a in the production of chiral, charged, peptide nucleic acid (PNA) molecules (e.g., see page 9 under “General method for synthesis of monomers”; and Figure 6). Nowhere in the specification, including the originally filed claims could explicit, implicit or inherent support be found for using the compounds of formula 4a or 6a for sequence specific recognition of nucleic acid molecules. It is noted that explicit support was found for using PNA molecules for sequence specific recognition of polynucleotide DNA or RNA molecules (e.g., see originally filed claim 9). Since support for using the compounds of formula 4a or 6a for sequence specific recognition of nucleic acid molecules could not be found in the specification, claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph.

Claims 22 and 23 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

*Wands* states on page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the

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invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The instant claims are drawn to a process for sequence specific recognition of a compound according to claim 14 or 15, respectively, wherein said compound is a single or double stranded polynucleotide DNA or RNA, comprising contacting a compound of formula 4a or 6a with a composition, and detecting a binding product comprising the compound of formula 4a or 6a in said composition.

As such, the claims encompass using the compounds of formula 4a or 6a (see claims 22 and 23 for formula 4a and 6a) for sequence specific recognition of a target nucleic acid molecule. (e.g., see page 9 under “General method for synthesis of monomers”; and Figure 6). The specification discloses that the compounds of formula 4a and 6a can be used in the synthesis of peptide nucleic acid molecules (e.g., see page 9 under “General method for synthesis of monomers”; and Figure 6). The specification also discloses that the peptide nucleic acid molecules which are produced using the compounds of formula 4a or 6a can bind to complementary DNA or RNA molecules. For instance, page 1 of the specification states,

“This invention is related to novel compounds derived from peptide nucleic acids that bind to complementary DNA and RNA strands. In particular the invention is concerned with peptide nucleic acid analogs that are chiral, positively charged, more soluble in aqueous systems and bind to complementary nucleic acid sequences with high avidity and sequence discrimination ability.”

The specification also states:

“It is one object of the present invention to provide cyclic monomers for peptide nucleic acid oligomers that bind single and double strand DNA to form stable hybrids with higher affinity, than the corresponding complexes of the standard peptide nucleic acids I composed from linear monomer units with DNA.

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It is another object of invention to provide monomers that are both cyclic and chiral for making oligomers that bind one strand of a double stranded polynucleotide, in a sequence and orientation specific manner.

It is yet another object of the invention to provide cyclic, chiral monomers that confer positive charge/s on the derived oligomers and make them more soluble in water than the standard peptide nucleic acids.

It is a further object to provide synthetic procedures for cyclic, chiral peptide nucleic acid monomers needed for the oligomers of the invention.” (See pages 3-4 of the specification).

Therefore, the specification discloses that the compounds of formula 4a and 6a are monomers that can be used in production of oligomers that bind to polynucleotide sequences. Furthermore, the specification does not appear to disclose that the monomer compounds of formula 4a or 6a can themselves be directly used in sequence specification recognition of polynucleotide molecules. The specification does not appear to disclose how the monomers of formula 4a or 6a could be used for sequence specific recognition of polynucleotide molecules. Based on the structure of the monomers as indicated in formula 4a or 6a, it does not appear that the monomers would be able to hybridize (e.g., form bonds hydrogen bonds) with target polynucleotide sequences, which is essential for sequence specific recognition of a polynucleotide sequence. Although, the level of skill in the art required to practice the claimed subject matter is high, the additional experimentation required to practice the claimed invention would be trial and error experimentation. Furthermore, the determination of how to use the monomers of formula 4a or 6a for sequence specific recognition of polynucleotide sequences would amount to an inventive step over the prior art. As such, the amount of additional experimentation required to practice the claimed invention to its full scope is undue.



***Allowable Subject Matter***

Claims 14-20, 24-26 are allowed.

***Response to Arguments***

Applicants' arguments filed 4/27/2006 (see page 9) are acknowledged. Applicants argue that the amendment to claims 22 and 23 overcome the rejection under 35 USC 112, second paragraph.

Applicant's arguments, with respect to the rejection(s) of claim(s) 22 and 23 under 35 U.S.C. 112, second paragraph/35 U.S.C. 101 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment to claims 22 and 23 which are drawn to the compound of claims 14 and 15, respectively, wherein the compound is a polynucleotide DNA or RNA molecule. As indicated above, claims 14 and 15 are drawn to peptide nucleic acid molecules, and do not encompass polynucleotide DNA or RNA molecules.

Also, upon further consideration, claims 22 and 23 have also been rejected under 35 USC 112, first paragraph (written description (new matter) and enablement) for the reasons indicated herein. This is a new grounds of rejection.

***Art of Interest***

It is noted that the chiral peptide nucleic acid molecules encompassed by the instant claims appear to be disclosed in U.S. Patent No. 6,716,961 B2 (e.g., see claims 1-10 of the issued patent). It is noted that the '961 patent was filed October 30, 2001, thus it is not prior art.

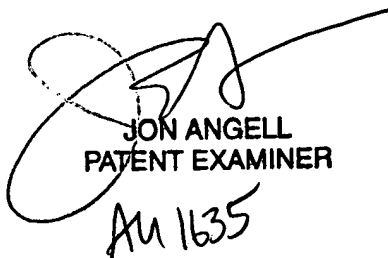
***Conclusion***

Since the 35 USC 112, first paragraph rejection(s) set forth herein is a new grounds of rejection not necessitated by amendment, this Action is made non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
JON ANGELL  
PATENT EXAMINER  
AU 1635